December 2, 2010

HIV/AIDS Bureau

Dear Ryan White HIV/AIDS Program Colleagues:

Last week, the National Institutes of Health announced the results of the international iPrEx clinical trial, co-sponsored by the Bill and Melinda Gates Foundation, that examined whether a pill containing two drugs used to treat HIV can also help prevent HIV infection – an approach called pre-exposure prophylaxis, or PrEP. The trial found that daily oral use of tenofovir plus emtricitabine (brand named Truvada®) provided an average of 44 percent (95% CI 15 to 63%) additional protection to trial participants that included gay, bisexual, and other men who have sex with men (MSM), as well as trans-gendered women who have sex with men. These participants also received a comprehensive package of prevention services that included monthly HIV testing, condom provision, counseling, and management of other sexually transmitted infections.

Ryan White HIV/AIDS Program funds cannot pay for PrEP as the person using PrEP is not HIV infected and therefore not eligible for Ryan White HIV/AIDS Program funded medication. It is important, however, that you share the following information with your medical providers so they are aware of the results and limitations of this clinical trial. It is highly likely that they will be approached either by their HIV negative non-Ryan White funded patients or by HIV infected patients and their discordant partners with questions regarding PrEP.

A key finding of this trial was that the level of protection individuals received from PrEP was dependent on how consistently participants used PrEP. Among those whose data (based on self-reports, bottles dispensed, and pill counts) indicates use on 90 percent or more days, HIV risk was reduced by roughly 73 percent (95% CI 41 to 88%); while among those whose adherence by the same measure was less than 90 percent, HIV risk was reduced by only 21 percent (95% CI, from 52% reduction to a 31% increase). Risk behavior among participants declined overall during the trial both in terms of decreases in the number of sexual partners and increases in condom use, likely as a result of the intensive risk reduction counseling provided as part of the trial.

While these trial results represent a significant advance in HIV prevention research, it is not time for anyone to abandon condoms or other proven risk reduction strategies. The investigators found that PrEP was only partially effective, and it cannot be seen as the first line of defense against HIV.

Given the severity of the HIV epidemic among MSM in the United States, another prevention tool with potential additive benefit is welcome news. Yet, additional research is needed to address the many real-world questions that remain to be answered, including feasibility, cost, and impact in non-trial settings. Success will depend on whether we can reach the MSM at highest risk for HIV and identify ways to achieve the high levels of drug adherence needed for maximum protection. It will also be critical that any use of PrEP take place in tandem with effective risk

reduction counseling, condoms, and other tools needed to prevent increases in risk behavior which could offset the benefits of PrEP. The impact of PrEP on the U.S. epidemic will depend on how effectively we utilize it in combination with all available treatment and prevention strategies.

To help ensure the safe, effective, and appropriate use of PrEP in the United States, the Centers for Disease Control and Prevention (CDC) will be developing detailed guidance for healthcare providers, public health agencies, and MSM. CDC will fully review the trial data and publish interim guidance in the coming weeks in the *Morbidity and Mortality Weekly Report,* to be followed in several months by formal U.S. Public Health Service guidelines. CDC urges individuals and their doctors to await those guidelines before use. However, Truvada® is widely available and frequently used for the treatment of persons with HIV infection, and CDC recognizes that some health care providers may receive immediate inquiries from individuals at high risk for HIV who are interested in using PrEP. Therefore, CDC offers the following initial cautions before guidelines are available:

- To date, PrEP has only been shown to reduce HIV infection among gay and bisexual men, and trans-gendered women who have sex with men, and there are no data regarding its benefit among heterosexuals or injection drug users.

- PrEP should only be used among individuals who have been confirmed to be HIV-negative. Initial and regular HIV testing is critical for anyone considering using PrEP. All individuals considering PrEP must also be evaluated for other health conditions that may impact PrEP use.

- PrEP should never be seen as the first line of defense against HIV. It was only shown to be partially effective when used in combination with regular HIV testing, condoms, and other proven prevention methods. Men who have sex with men should still:
    - Use condoms correctly and consistently
    - Get tested to know their status and that of their partner(s) for certain
    - Get tested – and treated if needed – for other sexually transmitted infections that can facilitate HIV transmission, such as syphilis and gonorrhea
    - Get information and support to reduce drug use and sexual risk behavior
    - Reduce their number of sexual partners

- Taking PrEP daily is critical. This study found that PrEP provided a high level of protection only to those who took the pills regularly; protection was very low among those who did not adhere to the daily regimen well.

- PrEP must be obtained and used in close collaboration with healthcare providers to ensure regular HIV testing, risk reduction and adherence counseling, and careful safety monitoring.

- Anyone considering using PrEP should speak with their doctor.

In closing, the results from the iPrEx study represent a significant research advance. However, the impact that PrEP will have on the U.S. HIV/AIDS epidemic is still largely unknown, as there are still many complex decisions and unknown elements related to implementing PrEP that will need to be studied and demonstrated in real-life settings. CDC has convened a trans-Health and Human Services workgroup (including the Health Resources and Services Administration) along with workgroups that include a wide variety of partners at national, State, and local levels to examine how to best use PrEP in combination with other prevention strategies to reduce new infections in the U.S. CDC will be examining the potential program costs, impact, and cost-effectiveness of PrEP compared to other interventions and will be pursuing a range of activities to address key unanswered questions and promote the effective and strategic use of PrEP.

As you are well aware, we already face significant unmet HIV treatment needs in this country and how to overcome those must also be considered as we explore all avenues to ensure appropriate use of PrEP. We also know that treatment alone will not be sufficient to end this epidemic and we must maximize the combined impact of all available strategies for prevention. For additional information, please refer to the CDC PrEP fact sheet: http://www.cdc.gov/nchhstp/newsroom/PrEPforHIVFactSheet.html. Updated information will be provided as it becomes available. If you have any questions, please contact your Project Officer.

Sincerely,

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